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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

In re ARDELYX, INC.	No. 4:21-cv-05868-HSG CLASS ACTION **THIRD AMENDED CLASS ACTION COMPLAINT** DEMAND FOR JURY TRIAL

Lead Plaintiff Jatin Malhotra ("Plaintiff") makes the following allegations, individually and on behalf of all others similarly situated, by and through Plaintiff's counsel, upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief is based upon, *inter alia*, counsel's investigation, which included, among other things, review and analysis of: (i) regulatory filings made by Ardelyx Inc. ("Ardelyx" or "Company") with the United States Securities and Exchange Commission ("SEC"); (ii) press releases and media reports issued and disseminated by the Company; (iii) analyst reports, media reports, and other publicly disclosed reports and information about the Company, including audio recordings from, and edited transcripts of, events during which the Company participated, and documents made publicly available by the United States Food and Drug Administration ("FDA"), including the Briefing Document the FDA published on November 16, 2022 concerning the events and omissions alleged herein, which is attached hereto as Exhibit A,[1] and (iv) conversations with individuals who witnessed the events alleged herein.[2] Plaintiff believes that substantial, additional evidentiary support will exist for the allegations set forth herein, after a reasonable opportunity for discovery.

SUMMARY OF THE ACTION

1. Plaintiff brings this federal securities action under §§10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act") and SEC Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5) on behalf of a class consisting of all persons and entities, other than Defendants herein and their affiliates, who purchased or otherwise acquired Ardelyx securities between May 7, 2020 and July 19, 2021, inclusive ("Class Period"), and who were damaged as a result of Defendants' violations of the Exchange Act ("Class").

[1] U.S. Food & Drug Admin., Cardiovascular and Renal Drugs Advisory Committee Meeting, *FDA Briefing Document, NDA # 213931*, at 11 (Nov. 16, 2022) (hereinafter "FDA Briefing Document").

[2] The event transcripts reviewed were obtained through BamSEC, an online database accessible to subscribers, and were edited and prepared by Thomson Reuters unless otherwise indicated. The audio recordings were accessed from the Bloomberg Terminal.

2. Plaintiff alleges that Defendants violated the Exchange Act by making false and misleading statements and omissions concerning (i) the Company's application for FDA approval of tenapanor as a monotherapy treatment for elevated serum phosphorus – a condition called hyperphosphatemia – in adult patients with chronic kidney disease ("CKD") on dialysis, and (ii) the strength and relevance of the data supporting the Company's FDA application. A chart setting forth Defendants' alleged misstatements and omissions is attached hereto as Exhibit B.

3. Ardelyx is a publicly traded biopharmaceutical company. During the Class Period, tenapanor was Ardelyx's leading product candidate. For this reason, the fate of Ardelyx's tenapanor application – *i.e.*, whether the FDA would approve or reject it – was integral to the value of Ardelyx securities.

4. On or about June 30, 2020, Ardelyx submitted a New Drug Application ("NDA") to the FDA to obtain approval to sell and market tenapanor for the treatment of hyperphosphatemia in adult CKD patients on dialysis. An NDA is the means by which a drug sponsor formally asks the FDA to approve a new drug for marketing and sale in the United States with respect to a given indication. The FDA accepted Ardelyx's NDA for review on or about September 15, 2020, and set a Prescription Drug User Fee Act ("PDUFA") date of April 29, 2021. A PDUFA date is the date by which the FDA must respond to an NDA.

5. Throughout the Class Period, without having any obligation to do so, Defendants chose to repeatedly assure the market that the FDA's approval was all but guaranteed because the meetings they were having with the FDA about the NDA were going "exceedingly well" and the FDA had not raised any issues that caused "concern" for the Company. For example, on November 17, 2020, speaking at an investor conference, Ardelyx's CEO, Defendant Mike Raab, stated with respect to the NDA, "***So we're quite confident with what it is that we've submitted***. ***The interactions [thus] far with the agency have gone exceedingly well*** . . . the confidence I have in the team and the confidence with the fact that they've seen the majority of this help a lot with

the uncertainty . . . ." [Emphasis added.[3]] On February 24, 2021, at another conference, Raab stated:

> ***So, we're about to see the fruits of our labor presumably with an approval around our PDUFA date*** and then embark on the commercialization for the product.
>
> * * *
>
> All the interactions that we've had thus far with the agency are standard ones that you have throughout the process of requests that they have for data or clarifications. But ***there's been nothing untoward and anything that causes us concern***.

[Emphasis added.[4]]

6. These statements were false and misleading because, contrary to Raab's misrepresentations, the Company's meetings with the FDA were not going "exceedingly well." Rather, in its meeting with the Company in March 2020, several months before the submission of the NDA itself, the FDA had pointedly set the evidentiary standard for approval of the NDA at a level that Ardelyx knew would be difficult, if not impossible, to meet in light of the clinical trial data that Ardelyx had. Specifically, from March 2020, the FDA consistently told the Company that the NDA would only be approved if the Company demonstrated that tenapanor had a clinically relevant treatment effect, which the Company could do by submitting (i) clinical data showing that tenapanor was at least as effective as existing treatments, meaning it caused a reduction of serum phosphorus in the range of 1.5 to 2.2. mg/dL, or (ii) evidence from a clinical outcome trial showing that tenapanor improved recipients' health. The glaring issue for Ardelyx during the Class Period was that it could not meet either of the FDA's requirements. Ardelyx's efficacy data showed that tenapanor was only one-third to one-half as effective as existing treatments, achieving a modest reduction of serum phosphorus of only 0.7 mg/dL, and Ardelyx did not conduct a clinical outcome trial.

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[3] *See* Transcript of Jefferies Virtual London Healthcare Conference at 4 (Nov. 17, 2020) (accessed via the Bloomberg Terminal).

[4] While the Thomson Reuters transcript available on BamSEC.com indicates that Defendant Raab said "unpoured," an audio recording of the same presentation accessed from the Bloomberg Terminal confirms Defendant Raab said "untoward."

7. These issues came to a head at the start of the Class Period when the FDA "clarified" for the Company at the March 2020 pre-NDA meeting that the NDA would not be approved unless it met the foregoing standards. At the time, Ardelyx had completed all three of the studies that it used to support the NDA, and therefore knew that the data showed only a modest reduction in serum phosphorus that did not meet the magnitude of effect standard enunciated by the FDA.

8. The fact that the NDA's approval was highly unlikely in light of the FDA's comments directly contradicted Raab's representations that the FDA and not said "anything" that "causes [] concern" and that conversations with the FDA were going "exceedingly well." Raab's representations assured investors that the FDA viewed the tenapanor NDA positively and that the efficacy data would be interpreted positively by the FDA. At the time these statements were made, Raab knew that the NDA did not contain data sufficient to show clinical relevance per the standard enunciated by the FDA. This fact called into question the basis for Raab's professed opinion because, in reality, the meetings with the FDA had raised a serious concern about the likelihood of and timeline for approval.

9. Rather than respond to the FDA's comments by addressing the evidentiary deficiency in the NDA, Raab decided to embark on a high-risk strategy of ignoring the FDA's comments with the goal of reversing the FDA's position either at the Division of Cardiology and Nephrology ("Division") level or on appeal. While Raab was free to choose this strategy even if the odds of success were low, he was not free to go out into the market and affirmatively tell investors that the FDA had said "nothing untoward" and had not said "anything" that causes "concern" because these representations were simply untrue.

10. Indeed, investors were extraordinarily misled by Defendants' misstatements. For example, in a November 23, 2020 analyst report, SVB Leerink wrote that there was a "95%" chance of "first-pass approval" for the tenapanor NDA. Cantor Fitzgerald assigned a "90%+" chance of approval. It wrote in a January 27, 2021 analyst report: "Today (1/27) we hosted a virtual Fireside Chat with the management team of ARDX (Mike Raab, President and CEO, Justin

Renz, CFO and David Rosenbaum, CMO). The takeaways from the event support our positive investment thesis on ARDX . . . We note the key highlights from our discussion below. . . ***ARDX does not see any significant outstanding risks that could result in a failure to obtain approval [for tenapanor] on its PDUFA date***." [Emphasis added.] On November 5, 2020, Piper Sandler assessed that "the setup to approval is overwhelmingly positive" based in part on "management's expectations that FDA will not require" a meeting of the Advisory Committee. These analyst reports underscore that there was a yawning gap between Defendants' representations about the regulatory proceedings and the reality – of which Defendants were fully aware – that the FDA's March 2020 comments directly called into question Ardelyx's ability to obtain approval.

11. On July 19, 2021, the Company announced that the FDA had rejected the tenapanor NDA for the exact reasons outlined in the March 2020 pre-NDA meeting. Critically, in its complete response letter, the FDA stated that it could not approve the NDA because "***the magnitude of the treatment effect is small and of unclear clinical significance.***" [Emphasis added.] The FDA further reiterated its direction that "[f]or this application to be approved, you will need to conduct an additional adequate and well-controlled trial demonstrating a clinically relevant treatment effect on serum phosphorus or an effect on a clinical outcome thought to be caused by hyperphosphatemia in CKD patients on dialysis."

12. Immediately following the Company's July 19, 2021 disclosure regarding the deficiencies of the clinical trial data offered to support the tenapanor NDA, market analysts cut their price targets and downgraded the Company's rating. Piper Sandler, for example, rated Ardelyx neutral (down from a buy-equivalent rating) and wrote, "we struggle to see a path forward for Tenapanor." Raymond James, another analyst, reset the Company's price target to $4, down from $14 per share. The Company's share price likewise plunged, falling $5.69 per share – or nearly 74% – in a single day, to close at $2.01 per share on July 20, 2021, before falling another 4.22% by market close on July 21, 2021.

13. In its subsequent correspondence, the FDA pointed to the fact that it had consistently told Ardelyx that the NDA would not be approved if the data submitted in support of

the NDA failed to show that tenapanor had a clinically relevant treatment effect, *i.e.*, a reduction in serum phosphorus comparable to existing treatments, or data from a clinical outcome trial. For example, in a February 4, 2022 letter, FDA Director Hylton Joffe wrote, "The Division informed you during the development process that the magnitude of phosphorus lowering with tenapanor needed to be sufficient to reasonably conclude there would be clinical benefit" and pointed to communications going back to November 9, 2017. In an April 15, 2022 letter, FDA Director Peter Stein wrote that the FDA had been "consistent" on the issue since November 2017 in telling Ardelyx that it would need to show serum phosphorus reduction in the range of 1.5 to 2.2. mg/dL in order to obtain approval.

14. Importantly, despite several subsequent declarations of victory, Ardelyx did not prevail on the issue of efficacy. Rather, Ardelyx quietly acquiesced to the FDA's view more than a year and a half later when it submitted a renewed NDA that only sought approval for treatment of hyperphosphatemia where existing, more effective treatments, were not working or not tolerated. This far narrower label – the subset of patients for whom existing treatments do not work – is a significantly smaller commercial opportunity.

15. This lawsuit seeks to recover damages sustained as a result of Defendants' wrongdoing.

JURISDICTION AND VENUE

16. The claims asserted herein arise under §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) & 78t(a)), and SEC Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5).

17. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and §27 of the Exchange Act (15 U.S.C. §78aa).

18. This Court has jurisdiction over each of the Defendants named herein because each is an individual or a corporation who has sufficient minimum contacts with this District so as to render the exercise of jurisdiction by the District Court permissible under traditional notions of fair play and substantial justice.

19. Venue is proper in this District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b). During the relevant period, Defendants conducted business in this District, and a substantial part of the events or omissions giving rise to the claims in this action – including Defendants' preparation and dissemination of materially false and misleading information as alleged herein – occurred in this District.

20. In connection with the acts, conduct, and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the U.S. mail, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

A. Plaintiff

21. Lead Plaintiff Jatin Malhotra, as set forth in his previously filed certification, acquired and held shares of Ardelyx common stock at artificially inflated prices during the Class Period, and has been damaged as a result of the violations of the federal securities law alleged herein. (*See* ECF No. 45-2.)

B. Defendants

22. Defendant Ardelyx is a specialized biopharmaceutical company incorporated under the laws of the state of Delaware. At all relevant times prior to October 2021, Ardelyx was co-headquartered in Fremont, California (at 34175 Ardenwood Boulevard, Fremont, California 94555) and Waltham, Massachusetts (at 400 Fifth Avenue, Suite 210, Waltham, Massachusetts 02451). As of October 2021, and currently, the Company maintains its headquarters in Waltham, Massachusetts. Ardelyx's common stock is listed on the NASDAQ under the ticker symbol "ARDX."

23. Defendant Mike Raab was, throughout the Class Period and at all relevant times, President and Chief Executive Officer of the Company, positions he held since March 2009. Defendant Raab also serves as a director on Ardelyx's Board of Directors. At the time he made the misstatements attributed to him, Defendant Raab knew that the FDA had set a standard for

showing the clinical relevance of tenapanor that the Company could not meet with the data it had. Raab, along with other senior Ardelyx officers, decided to ignore the FDA's comments and engage in a high stakes "game of chicken" with the Agency. Therefore, Raab knew that the NDA was at high risk of rejection or delay when he told investors that meetings with the FDA were going "exceedingly well" and that the FDA had said "nothing untoward" or "anything" that causes "concern." Furthermore, Defendant Raab had motive and opportunity to make his misstatements. As set forth below in the Additional Scienter Allegations section, Defendant Raab profited from the misstatements and omissions alleged herein by selling stock while the price of Ardelyx was inflated by his misstatements.

24. Defendant David Rosenbaum was, throughout the Class Period and at all relevant times, Chief Development Officer of the Company, a position he held since January 2015. Defendant Rosenbaum knew that the FDA had set a standard for showing clinical relevance that the Company could not meet with the data it had because Rosenbaum attended the March 2020 pre-NDA meeting where the FDA delivered this message.

25. Together, Defendants Raab and Rosenbaum are referred to herein as the "Individual Defendants." The Individual Defendants, because of their positions at the Company, possessed the power and authority to control the content and form of the Company's annual reports, quarterly reports, press releases, investor presentations, and other materials provided to the SEC, securities analysts, money and portfolio managers, and investors, *i.e.*, the market. The Individual Defendants authorized the publication of the documents, presentations, and materials alleged herein to be misleading prior to their issuance and had the ability and opportunity to prevent the issuance of these false statements, or to cause them to be corrected. Because of their position with the Company and access to material non-public information that was available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public and that the positive representations being made were false and misleading. The Individual Defendants are liable for the false statements pleaded herein.

SUBSTANTIVE ALLEGATIONS

I. TENAPANOR WAS CRITICAL TO ARDELYX'S FINANCIAL SUCCESS

26. Founded in 2007, Ardelyx is a biotechnology company focused on developing and commercializing therapies for, among other things, persons with kidney and cardiorenal disease. Ardelyx has been publicly traded since June 2014, and has not earned a profit in any fiscal year. Accordingly, at all relevant times, Ardelyx's financial well-being heavily depended on the commercial success of tenapanor for the treatment of hyperphosphatemia in adults with CKD who were on dialysis.

27. Ardelyx considers tenapanor its "lead product candidate." Ardelyx initially began developing tenapanor in or about 2009, to treat irritable bowel syndrome ("IBS") associated with constipation. For that indication only, Ardelyx obtained FDA approval in or about September 2019, to market and sell tenapanor in the United States, but, as of the start of the Class Period, the Company had neither commercialized nor generated any significant revenue from its sale for that indication. This made the success of the NDA for hyperphosphatemia, and subsequent commercialization of tenapanor as a treatment for hyperphosphatemia in adult CKD patients on dialysis, even more important for Ardelyx.

28. In the context of that indication, tenapanor represented a potential first-in-class therapy because of its novel mechanism of action. Extant medicines that treat hyperphosphatemia in adult CKD patients on dialysis act through the mechanism of binding to phosphates that enter the body. Tenapanor, by contrast, acts through the mechanism of inhibiting the paracellular uptake of phosphates. According to Ardelyx, tenapanor has "a unique mechanism of action and acts locally in the gut to inhibit the sodium hydrogen exchanger 3, or NHE3," resulting in the "tightening of the epithelial cell junctions, thereby significantly reducing paracellular uptake of phosphate, the primary pathway of phosphate absorption."

29. If approved for the treatment of hyperphosphatemia, according to Ardelyx, tenapanor "would be the first therapy for phosphate management that blocks phosphorus absorption at the primary pathway of uptake," and "could greatly improve patient adherence and

compliance with one single pill dosed twice daily in contrast to current therapies where typically multiple pills are taken before every meal."

30. Thus, as presented by Defendants, obtaining FDA approval for tenapanor for treating hyperphosphatemia represented, and continues to represent, a lucrative commercial opportunity. The importance of that opportunity for Ardelyx was compounded by the Company's historical inability to report a profitable quarter as a publicly traded company.

II. ARDELYX'S NDA FOR TENAPANOR FOR HYPERPHOSPHATEMIA

A. The Studies Ardelyx Used to Support Its NDA Used a Surrogate Endpoint to Measure Efficacy

31. Ardelyx supported the NDA with efficacy data generated from three clinical trials. The ability of tenapanor to lower serum phosphorus when administered as a monotherapy in adult subjects with CKD on dialysis was evaluated in two randomized multicenter studies (the phase 2b study TEN-02-201 and the phase 3 study TEN-02-301). A third study (study TEN-02-202) evaluated the efficacy of tenapanor as adjunctive therapy to phosphate binder treatment.

32. In general, a clinical trial uses a particular clinical trial endpoint to measure the results of the trial. An endpoint that directly measures the proposed clinical benefit of a therapy, such as reduced morbidity or mortality, is called a clinical outcome endpoint. An endpoint that measures something other than a clinical outcome is called a surrogate endpoint. A surrogate endpoint, in turn, must be shown to reliably predict the clinical benefit of a proposed therapy by virtue of the measured changes in the surrogate endpoint because, by design, a surrogate endpoint does not directly measure the clinical benefit.

33. Certain surrogate endpoints belong to the subclass called biomarkers. In general, a biomarker is a defined characteristic that is measured objectively as an indicator of the body's response to an exposure or intervention, including a therapeutic intervention.

34. Each of the trials that Ardelyx used to support the tenapanor NDA used a surrogate endpoint instead of a clinical outcome endpoint. The relevant surrogate endpoints all related to levels of serum phosphates measured in trial participants (which may be further characterized as biomarkers). That means the trials measured the changes in serum phosphorus among participants

that could be attributed to the use of tenapanor. By design, the trials did not measure whether, or to what extent, any clinical benefits flowed from those changes in serum phosphorus, such as reduced morbidity or mortality.

B. By the Start of the Class Period, Defendants Knew That the FDA Set a Standard for Approval That Ardelyx Could Not Meet with the Data It Had

35. During the course of the development process, the FDA communicated its expectations to the Company regarding the efficacy data that would be needed to support approval of the NDA. As the FDA later disclosed, "over the course of product development, there were a number of discussions with the Applicant about the design of the tenapanor development program ***and the data needed to demonstrate efficacy and safety***."[5] [Emphasis added.] Throughout these conversations going back to November 2017, the FDA was "consistent" in its position that Ardelyx would need to submit evidence that the magnitude of tenapanor's treatment effect was clinically relevant.

36. In November 2017, the FDA provided Ardelyx with feedback on the protocol and statistical analysis plan for Ardelyx's Phase 3 Study TEN-02-301. In the Advice Letter, FDA advised, "If the size of the effect of tenapanor on serum phosphorous is significantly smaller than the size of the effect of currently approved phosphate binders, then you will need to address the clinical relevance of the effect size of your product on serum phosphorous."[6] As the FDA stated, these and other comments by it "must be read in the context of prior statements by the Division pointing to the effect sizes seen across all other approved agents of at least 1.5 mg/dL" for the intention to treat or "ITT" population.[7] Given this context, the FDA's meaning is clear: either tenapanor would have to demonstrate a serum phosphorus reduction comparable to existing treatments or the Company needed to come forward with other data showing clinical relevance, such as data from a clinical outcome study.

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5 *See* FDA Briefing Document.

6 *Id.*

7 *Id.* at 68.

37. In December 2018, the FDA issued another "Advice Letter" in response to Ardelyx's request for feedback on Study TEN-02-202, which evaluated the efficacy of tenapanor as adjunctive therapy to phosphate binder treatment in end-stage renal disease subjects with hyperphosphatemia. Ardelyx's request pertained to labeling questions, specifically, whether the results of the study could support additional labeling claims. In response, the FDA very pointedly qualified its remarks by stating, in pertinent part, "***Assuming*** the trial is well-conducted and ***the size of the treatment effect is clinically relevant***, we agree that the results could be described in labeling."[8] [Emphasis added.]

38. The FDA's consistent position that the Company had to demonstrate tenapanor's clinical relevance by matching the reduction in serum phosphorus established in existing treatments or through data from an outcome trial was obviously a huge hurdle for the NDA because tenapanor was far less effective at reducing serum phosphorus than existing treatments. Products that had already been approved for the treatment of hyperphosphatemia reduced serum phosphorus at a range of 1.5 to 2.2 mg/dL.[9] By contrast, in the studies performed by Ardelyx, tenapanor reduced serum phosphorus at a rate of 0.7 mg/dL.[10] In other words, the data showed that tenapanor was between one-third and one-half as effective as existing treatments. Therefore, based on the data Defendants had and repeated statements from the FDA pointing to the efficacy of existing products as the standard, Defendants knew that Ardelyx could not meet the FDA's standard for showing clinical relevance through evidence of the magnitude of tenapanor's treatment effect.

39. The reasons for the FDA's position are twofold. First, the FDA determined that the precedent set by previously approved treatments set a helpful standard for measurement.[11] Second, the Division believed that tenapanor being much less effective than existing treatments

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[8] *Id.* at 11.

[9] *Id.* at 6.

[10] *Id.* at 7.

[11] U.S. Food & Drug Admin., *Transcript of Cardiovascular and Renal Drugs Advisory Committee (CRDAC) Meeting*, at 130 (Nov. 16, 2022) [hereinafter FDA Transcript], https://www.fda.gov/media/165302/download.

could delay or possibly prevent patients from reaching their target level of serum phosphorus.[12] These concerns were particularly acute for tenapanor due to its modest effect and the variability in serum phosphorus measurements, two factors that would make it difficult for clinicians to discern whether an individual patient is experiencing the desired response.[13]

40. The other way that a company could demonstrate clinical relevance is through data from an outcome study showing that the use of tenapanor leads to better health outcomes, such as lower mortality, among patients. But as Defendants knew, Ardelyx had not performed such a study and any such study would require an extended delay on the path to approval, not to mention a tremendous outlay of resources.

41. The issues regarding the sufficiency of Ardelyx's NDA came to a head during the March 2020 pre-NDA meeting with the FDA. The meeting was attended by several senior Ardelyx officials and FDA personnel. The meeting occurred at FDA headquarters in Maryland and the Ardelyx officials that attended included Chief Scientific Officer Jeff Jacobs, Chief Regulatory Officer Rob Blanks, Senior Director of Pharmaceutical Chemistry and Formulations Sanjeev Khotari, and Chief Development Officer David Rosenbaum. Also present on behalf of Ardelyx was Dr. Glenn Chertow, Division Chief of Nephrology and Professor of Medicine at Stanford University. FDA attendees included senior members of the Office of Cardiology, Hematology, Endocrinology, and Nephrology ("OCHEN") including OCHEN Director Dr. Ellis Unger and Deputy Director Dr. Aliza "Lisa" Thompson.

42. The meeting occurred after the conclusion of all clinical trials associated with the forthcoming tenapanor NDA. TEN-02-201 was completed on January 17, 2018; TEN-02-202 was completed on July 17, 2019; and TEN-02-301 was completed on February 27, 2020. Thus, at the time of the meeting, Defendants had the relevant data and knew what it showed in terms of efficacy. Pre-NDA meetings occur no less than 60 days prior to the NDA filing. "The primary purpose" of pre-NDA meetings "is to uncover any major unresolved problems, to identify those

[12] *Id.* at 28:14–19.

[13] *Id.* at 28:20–29:5.

studies that the sponsor is relying on as adequate and well-controlled to establish the drug's effectiveness, . . . to acquaint FDA reviewers with the general information to be submitted in the marketing application (including technical information), . . . and to discuss the best approach to the presentation and formatting of data in the marketing application."[14] Here, any reasonable person receiving the message the FDA had consistently delivered by this point would understand that the NDA was in serious jeopardy unless the Company conducted an additional study to demonstrate efficacy – *i.e.*, a greater reduction in serum phosphorus levels, comparable to existing therapies – or some positive relationship between reduced serum phosphorus and a clinical outcome.

43. The March 2020 pre-NDA meeting focused on questions about tenapanor's efficacy in treating hyperphosphatemia in adult CKD patients on dialysis. Specifically, the FDA raised the concern that the magnitude of the treatment effect as shown in the clinical trials may not be clinically relevant given tenapanor's modest effect on serum phosphorus. Indeed, during this meeting, the FDA clearly informed Ardelyx that while it had accepted serum phosphorus as a surrogate endpoint, a "treatment effect of any magnitude is not considered sufficient to support [NDA] approval."[15]

44. During the pre-NDA meeting, these clinical issues were discussed at length. The FDA's summary of the meeting states:

> "The Agency indicated that it has accepted serum phosphorus as a surrogate endpoint and basis for approval for products intended to treat hyperphosphatemia in patients with chronic kidney disease in dialysis. The evidence supporting its use as a surrogate endpoint includes biologic plausibility and epidemiologic data; ***but,*** to date there is no evidence from outcome studies demonstrating that a treatment's effect on serum phosphorus predicts its effects on clinical outcomes." ***The Agency clarified, however, that while it has accepted serum phosphorus as a surrogate endpoint, a treatment effect of any magnitude is not considered sufficient to support approval***.
>
> The Agency indicated that the Applicant should address the clinical relevance of the magnitude of the treatment effect observed in their development program in their NDA submissions. ***The Agency stated that it is interested in evidence***

[14] 21 C.F.R. §312.47(b)(2).

[15] FDA Briefing Document at 12.

> ***supporting the conclusion that the magnitude of the treatment effect is clinically relevant, as opposed to "expert opinion."*** The Agency also stated that showing a marked treatment effect in patients with more marked elevations in s-P level at baseline could be compelling.[16]

[Emphasis added.]

45. This summary of the meeting provided by the FDA reflects the FDA's demand – which, from Ardelyx's perspective, was highly problematic – that Ardelyx support its NDA with data showing that tenapanor was as effective as existing treatments in reducing serum phosphorus or with clinical outcome data. The FDA expressly "clarified" to Ardelyx that the NDA would not be approved without such evidence.

46. Indeed, the FDA has confirmed that this was the message it gave to Ardelyx during the development process. As stated in the February 4, 2022 letter from the FDA to Ardelyx, beginning in November 2017, "the Division informed you during the development that the magnitude of phosphorus lowering tenapanor needed to be sufficient to reasonably conclude there would be clinical benefit."[17] The NDA failed to meet this requirement because it only showed "modest mean reductions in serum phosphorus."[18] As stated in the April 15, 2022 letter from the FDA:

> In the complete response letter dated July 28, 2021 . . . The Division acknowledged that they accept lowering serum phosphate as a validated surrogate endpoint but consider that the *extent of* effect is relevant to an approval decision. ***It is important to observe that the Division's perspective on this point has been consistent, having previously informed the company that a justification for an effect size smaller than seen with approved agents would be needed, noting that approved drugs provide reductions in serum phosphate concentrations in the 1.5-2.2 mg/dL range***.[19]

[Emphasis added.]

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16 *Id.*

17 *Id.* at 50–51.

18 *Id.* at 51.

19 *Id.* at 63.

47. Also during the March 2020 meeting, the FDA made clear that it would not approve the NDA on the basis of the "expert opinion" offered by Ardelyx. Rather, Ardelyx would need to demonstrate efficacy through actual data. The reference to expert opinion in the minutes is a reference to the opinions of Dr. Chertow and other nephrologists. During the March 2020 meeting, Dr. Chertow argued that tenapanor could add value because it had less frequent side effects than sevelamer, a phosphate-binder medication that had already been approved for lowering serum phosphate but that frequently causes gastrointestinal issues. Dr. Chertow also emphasized the reduced pill burden of tenapanor versus sevelamer. Whereas patients using sevelamer take eight tablets per day, tenapanor requires only two. The FDA's summary of the March 2020 meeting reflects its communication that these types of opinions were insufficient to support approval because they were not supported by actual data from, for example, clinical outcome trials. Rather, Dr. Chertow's opinions were based on his observations in the field.

48. The problematic nature of the FDA's comments during the March 2020 pre-NDA meeting was not lost on Ardelyx officials. At least one Ardelyx official who attended the meeting interpreted the comments of Dr. Thompson, who led the discussion on behalf of the FDA, as giving rise to a potential objection that could lead to outright rejection of the NDA if the efficacy concerns raised by Dr. Thompson were not addressed. The FDA's key point was that Ardelyx needed to provide more compelling, quantifiable evidence of clinical relevance. The implication of Dr. Thompson's comments during the pre-NDA meeting was that, in light of the efficacy data, the Company would need to perform a new study to show reduced serum phosphorus being associated with improved clinical outcomes in order to obtain approval. Other Ardelyx executives expressed some frustration after the meeting.

49. Defendant Raab was aware that during the pre-NDA meeting, the FDA had set an evidentiary standard for approval that would be difficult if not impossible for the Company to meet with its current data set from its clinical trials. Defendant Raab had conversations with other senior Ardelyx officials regarding the FDA's comments and how Ardelyx should respond. Nevertheless,

Defendant Raab and Ardelyx's other senior leadership decided to ignore the FDA's comments and just move forward with the NDA notwithstanding the high risk of rejection.

50. On August 6, 2020, in a press release titled "Ardelyx Reports Second Quarter 2020 Financial Results and Recent Business Highlights," Ardelyx announced that on June 30, 2020, it submitted an NDA to the FDA for tenapanor for the treatment of hyperphosphatemia in adult CKD patients on dialysis. The Company reported substantially the same news in its quarterly report on Form 10-Q for the period ending June 30, 2020, which it filed with the SEC the same day.

51. On September 15, 2020, Ardelyx announced that the FDA had accepted, or agreed to review, its NDA for tenapanor for the treatment of hyperphosphatemia in adult CKD patients on dialysis. The Company did so in a press release titled "Ardelyx Announces FDA Acceptance for Filing of Its New Drug Application of Tenapanor for the Control of Serum Phosphorus in Adult Patients with CKD on Dialysis." Also in that press release, Ardelyx relayed that the FDA had set a PDUFA date – *i.e.*, the date by which the FDA would respond to the NDA – of April 29, 2021.

52. On April 29, 2021, roughly ten months after Ardelyx submitted the tenapanor NDA, the Company announced that the FDA pushed back the PDUFA date it initially set by three months. In the relevant press release the Company issued, titled "Ardelyx Announces Extension of the PDUFA Review Period for Tenapanor for the Control of Serum Phosphorus in Adult Patients with CKD on Dialysis," Ardelyx stated that the FDA "made a recent information request that required the company to submit additional analyses to help the agency better understand the clinical data in light of tenapanor's novel mechanism of action as compared to approved therapies." According to Ardelyx, that information request came after the parties already had begun "constructive labeling discussions" regarding tenapanor which, if true, would have been a positive development. "Labeling discussions" refers to the process for determining what disclosures, warnings, and other information must be included with a drug when it is sold to patients.

53. The next key update Ardelyx provided on the tenapanor NDA occurred several months later, on July 19, 2021, when the Company announced that the FDA had sent it a letter six days earlier (on July 13, 2021) in which the agency "identified deficiencies that preclude[d]

discussion of labeling and post-marketing requirements" for tenapanor. The "deficiencies" the FDA identified included, according to Ardelyx, "the size of the treatment effect and its clinical relevance" pursuant to the Phase 3 Trials. The Company made that update in a press release titled "Ardelyx Provides Regulatory Update on New Drug Application for Tenapanor for the Control of Serum Phosphorus in Adult Patients with CKD on Dialysis."

III. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS

54. Throughout the Class Period, Defendants misleadingly portrayed the FDA as having acquiesced to Ardelyx's NDA approach, such that approval was all but assured. Contrary to Defendants' representations, the reality was that the FDA had set the bar for approval of the NDA in a way that raised serious doubts about the viability of the NDA. Specifically, Defendants knew that the FDA had emphasized that approval was unlikely unless the Company was able to prove that tenapanor had a clinically relevant treatment effect by pointing to (i) a treatment effect of reduced serum phosphorus comparable to existing treatments, or (ii) data from a clinical outcome trial. Defendants further knew that they did not have data that could satisfy the FDA's requirement because the efficacy data for tenapanor showed that it was one-third to one-half as effective as existing treatments and that Ardelyx had declined to perform an outcome study. A chart of alleged misstatements and omissions is attached hereto as Exhibit B.

A. May 7, 2020 Press Release

55. In a May 7, 2020 press release, the Company stated the following:

> **Preparing NDA Submission for Tenapanor for the Control of Serum Phosphorus in mid-2020**: With ***strong data from its clinical program for tenapanor***, Ardelyx is preparing a New Drug Application for tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis, which the company currently intends to submit to the U.S. Food and Drug Administration in mid-2020.

[Emphasis added.]

56. The assertion by the Company that the NDA was supported by "strong data" from the "clinical program" is misleading in context because Defendants were aware of undisclosed facts that seriously undermined the statement's accuracy and that rendered the statement as lacking

a reasonable basis. A reasonable investor informed of Phase III trial results involving "strong data" would expect that the speaker had a factual basis for its belief that such results were relevant or meaningful. Such an investor would expect that the speaker's proposed interpretation of trial results had not already been undermined by the agency tasked with evaluating the NDA. Here, Defendants knew but failed to disclose that the FDA had already undermined Ardelyx's proposed interpretation of its efficacy data and, therefore, that the Company's data could not reasonably be characterized as "strong." In the March 2020 pre-NDA meeting, the FDA told Ardelyx that its NDA would not be approved without evidence of a clinically meaningful treatment effect. The FDA had further discussed with Ardelyx the type of data that would suffice: (i) evidence of a treatment effect comparable to effects achieved by existing treatments, or (ii) data from clinical outcome trials. Defendants knew that they did not have either type of data. The efficacy data for tenapanor showed it to be one-third to one-half as effective as existing treatments and the Company had not done an outcome study. Thus, as discussed with the FDA in March 2020, Ardelyx faced a high chance of failure and delay.

B. August 6, 2020 Quarterly Report

57. On August 6, 2020, Ardelyx filed with the SEC its quarterly report on Form 10-Q for the period ending June 30, 2020 ("2Q20 10-Q"). In relevant part, with respect to the tenapanor NDA and underlying Phase 3 Trials, the 2Q20 10-Q stated:

> Our portfolio is led by the development of tenapanor, a first-in-class medicine for the control of serum phosphorus in adult patients with CKD on dialysis, for which we completed the Phase 3 clinical program and have submitted a New Drug Application ("NDA") to the United States Food and Drug Administration ("FDA") on June 30, 2020. Based on standard FDA review timelines, we expect to receive notification from the FDA on the acceptance of the filing for substantive review by early September 2020. Tenapanor for the control of serum phosphorus has a unique mechanism of action and acts locally in the gut to inhibit the sodium hydrogen exchanger 3 ("NHE3"). This results in the tightening of the epithelial cell junctions, thereby significantly reducing paracellular uptake of phosphate, the primary pathway of phosphate absorption. Three successful Phase 3 studies demonstrating tenapanor's ability to reduce phosphate levels, as either monotherapy or as part of a dual mechanism approach with phosphate binders, have been reported.
>
> * * *

> Tenapanor, if approved, would be the first therapy for phosphate management that blocks phosphorus absorption at the primary pathway of uptake. It is not a phosphate binder. Tenapanor is a novel, potent, small molecule, that ***has been shown in the phase 3 studies to treat hyperphosphatemia as monotherapy and as a dual mechanism approach***. Additionally, as such we believe tenapanor could greatly improve patient adherence and compliance with one single pill dosed twice daily in contrast to current therapies where typically multiple pills are taken before every meal.

[Emphasis added.]

58. The assertion that the Company's "phase 3 studies" had "shown" that tenapanor treated hyperphosphatemia as a monotherapy was misleading because Defendants were aware of undisclosed facts that seriously undermined the statement's accuracy and that rendered the statement as lacking a reasonable basis. A reasonable investor informed that Phase III trial results had "shown" something to be the case would expect that the speaker had a factual basis for its belief that such results were relevant or meaningful. Such an investor would expect that the speaker's proposed interpretation of trial results had not already been undermined by the agency tasked with evaluating the NDA. Here, Defendants knew but failed to disclose that the FDA had already indicated that tenapanor's efficacy data was insufficient to support approval. In the March 2020 pre-NDA meeting, the FDA told Ardelyx that its NDA would not be approved without evidence of a clinically meaningful treatment effect. The FDA had further discussed with Ardelyx the type of data that would suffice: (i) evidence of a treatment effect comparable to effects achieved by existing treatments, or (ii) data from clinical outcome trials. Defendants knew that they did not have either type of data. The efficacy data for tenapanor showed it to be one-third to one-half as effective as existing treatments and the Company had not done an outcome study. Thus, as discussed with the FDA in March 2020, Ardelyx faced a high chance of failure and delay.

C. August 6, 2020 Press Release

59. The same day, in the Company's press release accompanying its 2Q20 10-Q, Ardelyx announced that it had submitted the tenapanor NDA to the FDA "for the review of tenapanor as a first-in-class therapy to control serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis." Quoting Defendant Raab, the press release stated:

> "Over the last quarter, we continued to make critical progress towards our goal of providing our first-in-class therapy tenapanor to adult CKD patients on dialysis with elevated serum phosphorus, a condition, despite traditional therapies, that has been associated with poor survival outcomes," said Mike Raab, president and chief executive officer of Ardelyx. "This past June, we submitted a New Drug Application to the FDA for this indication, and we expect to receive notification of its acceptance for substantive review and our PDUFA date by early September. ***As part of our filing, we included additional, robust data reconfirming tenapanor's ability to lower and control serum phosphorous levels at a rate better than those reported with phosphate binders alone***. In addition, during the quarter, we augmented our senior leadership team with the hiring of an experienced chief commercial officer and chief financial officer as we prepare for launch and evolving into a revenue-generating company."

[Emphasis added.]

60. Under the heading "Recent Business and Pipeline Updates," the August 6, 2020 press release also stated that the NDA "filing is supported by ***three successful Phase 3 studies*** demonstrating tenapanor's ability to reduce phosphate levels, with two trials evaluating tenapanor as a monotherapy and the third evaluating tenapanor as part of a dual mechanism approach with phosphate binders." The press release also reported "additional positive data from the ongoing NORMALIZE Phase 4 study," which was an extension of one of the three clinical trials that remained ongoing. [Emphasis added.]

61. The representations that the Company's data was "robust" and that its Phase 3 studies were "successful" were misleading in light of the failure to disclose the FDA's requirement that Ardelyx demonstrate a clinically relevant treatment effect as defined by (i) serum phosphorus reduction in the range of 1.5 to 2.2 mg/dL, or (ii) data from an outcome trial. These facts seriously undermined the accuracy of these statements and rendered them as lacking a reasonable basis. A reasonable investor would find it highly material that the trials were not "successful" per the approval standard set forth by the FDA and that the data was not "robust" per the same standard because a reasonable investor cares about the likelihood and timeline for the approval of the NDA. By failing to disclose known facts showing that the risk of rejection or delay was much higher than they let on, Defendants misled investors with their statements.

D. November 5, 2020 Quarterly Report

62. On November 5, 2020, Ardelyx filed with the SEC, on Form 10-Q, its third quarter 2020 financial results ("3Q20 10-Q"), repeating substantially the same claims made in the Company's 2Q20 10-Q with respect to the tenapanor NDA and underlying Phase 3 Trials. In relevant part, the 3Q20 10-Q stated:

> ***The NDA is supported by three successful Phase 3 trials*** involving over 1,000 patients that evaluated the use of tenapanor for the control of serum phosphorus in CKD patients on dialysis, with two trials evaluating tenapanor as monotherapy and one trial evaluating tenapanor as part of a dual mechanism approach with binders.
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> * * *
>
> In December 2019, ***we reported statistically significant topline efficacy results from our second monotherapy Phase 3 clinical trial***, the PHREEDOM trial, which evaluated tenapanor for the control of serum phosphorus in CKD patients on dialysis. The PHREEDOM trial followed ***a successful monotherapy Phase 3 clinical trial completed in 2017, which achieved statistical significance for the primary endpoint***. PHREEDOM is a one-year study with a 26-week open-label treatment period and a 12-week double-blind, placebo-controlled randomized withdrawal period followed by a 14-week open-label safety extension period. An active safety control group, for safety analysis only, received sevelamer, open-label, for the entire 52-week study period. Patients completing the PHREEDOM trial from both the tenapanor arm and the sevelamer active safety control arm had the option to participate in NORMALIZE, an ongoing open-label 18-month extension study.
>
> * * *
>
> Tenapanor, if approved, would be the first therapy for phosphate management that blocks phosphorus absorption at the primary pathway of uptake. It is not a phosphate binder. Tenapanor is a novel, potent, small molecule, that ***has been shown in the phase 3 studies to treat hyperphosphatemia as monotherapy and as a dual mechanism approach***. Additionally, we believe tenapanor could greatly improve patient adherence and compliance with one single pill dosed twice daily in contrast to current therapies where typically multiple pills are taken before every meal.

[Emphasis added.]

63. The representation that Ardelyx's Phase 3 trials were "successful" and that the Company's "phase 3 studies" had "shown" that tenapanor treated hyperphosphatemia as a monotherapy were false and misleading because Defendants were aware of undisclosed facts that

seriously undermined the statement's accuracy and that rendered the statement as lacking a reasonable basis. A reasonable investor informed that Phase III trial results had "shown" something to be the case would expect that the speaker had a factual basis for its belief that such results were relevant or meaningful. Such an investor would expect that the speaker's proposed interpretation of trial results had not already been undermined by the agency tasked with evaluating the NDA. Here, Defendants knew but failed to disclose that the FDA had already indicated that tenapanor's efficacy data was insufficient to support approval. In the March 2020 pre-NDA meeting, the FDA told Ardelyx that its NDA would not be approved without evidence of a clinically meaningful treatment effect. The FDA had further discussed with Ardelyx the type of data that would suffice: (i) evidence of a treatment effect comparable to effects achieved by existing treatments, or (ii) data from clinical outcome trials. Defendants knew that they did not have either type of data. The efficacy data for tenapanor showed it to be one-third to one-half as effective as existing treatments and the Company had not done an outcome study. Thus, as discussed with the FDA in March 2020, Ardelyx faced a high chance of failure and delay.

E. November 5, 2020 Press Release

64. The Company issued a November 5, 2020 press release accompanying the 3Q20 10-Q titled "Ardelyx Reports Third Quarter 2020 Financial Results and Business Highlights." Under the heading "Recent Business and Pipeline Updates," the November 5, 2020 press release also stated:

> The United States Food and Drug Administration (FDA) accepted the New Drug Application (NDA) for tenapanor to control serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis with a Prescription Drug User Fee Act ("PDUFA") goal date of April 29, 2021. ***The filing was supported by three successful Phase 3 studies demonstrating tenapanor's ability to reduce phosphate levels***, with two trials evaluating tenapanor as a monotherapy and the third evaluating tenapanor as part of a dual mechanism approach with phosphate binders.

[Emphasis added.]

65. The representation that the Company's Phase 3 studies were "successful" was false and misleading in light of the failure to disclose the FDA's requirement that Ardelyx demonstrate a clinically relevant treatment effect as defined by (i) serum phosphorus reduction in the range of

1.5 to 2.2 mg/dL, or (ii) data from an outcome trial. These facts seriously undermined the accuracy of these statements and rendered them as lacking a reasonable basis. A reasonable investor would find it highly material that the trials were not "successful" per the approval standard set forth by FDA because a reasonable investor cares about the likelihood and timeline for the approval of the NDA. By failing to disclose known facts showing that the risk of rejection or delay was much higher than they let on, Defendants misled investors with their statements.

F. November 17, 2020 Investor Presentation

66. Defendants Raab and Rosenbaum gave a presentation to investors, on behalf of Ardelyx, in question-and-answer format, at the Jefferies Virtual London Healthcare Conference on November 17, 2020. Ardelyx published notice that the Company would be making that presentation – which it called a "fireside chat" – in a November 10, 2020 press release titled "Ardelyx to Present at the Jefferies Virtual London Healthcare Conference."

67. During the presentation, a participant asked about the clinical development program Ardelyx was conducting for the tenapanor NDA. In response, Defendant Rosenbaum stated that the data from the clinical trials established that administering tenapanor produced "a significant and clinically relevant phosphate lowering":

> Q – . . . . But David for the clinical program, I guess what is the goal? What is it that we're trying to do for these patients? And how in your view did your clinical program demonstrate [ ] the achievement of those goals?
>
> A – [Rosenbaum] Sure. So first it's well known a lot of prospective observational studies that have shown an association with elevate[d] [serum phosphorus] and morbidity [and] mortality. A lot of studies have shown that, so what our goal here is to lower serum phosphorus. And we've shown – we've run as Mike said three Phase 3 clinical trials two short term one long term. ***And what we've shown is that if you dose tenapanor [alone], you get a significant and clinically relevant phosphate lowering***. In our long-term phase 3, which is the most relevant study, we showed that 77% [of] people administered tenapanor had a decrease in serum phosphorus and there was a 2 mg/dL decrease. So that's a very significant effect.
>
> * * *
>
> And those on tenapanor, we automatically add tenapanor and allow them to titrate off of [sevelamer] to see how many we can get into the normal range. And people who end up st[a]ying from the beginning of [PHREEDOM] had a mean[] prosperous [level] of 7.27 mgs per deciliter. After [a] mean duration of around 19 to 20 months, they went down to 4.94. And so they had over 2.3 mg definitely

> decrease and we were able to get up to 47% of those people into the normal range. So around [a] 60% increase over standard of c[a]re. ***So, what that – totality of that data [has] shown is that you can treat a lot of people with tenapanor alone and it will work well***.[20]

[Emphasis added.]

68. The representation that the Company had "shown" that tenapanor provides a "significant and clinically relevant phosphate lowering" was misleading in light of the failure to disclose that the FDA took a different view. As Defendants knew, the relatively small effect achieved by tenapanor was of dubious clinical value and did not meet the standards for approval that the FDA had consistently set forth throughout the development process. These undisclosed facts significantly undercut Defendants' representations and rendered them as without a reasonable basis.

69. During the same presentation, a participant asked about the status of Ardelyx's tenapanor NDA, in response to which Defendant Raab stated that relevant divisions of the FDA "ha[d] already seen" certain information in the tenapanor NDA by virtue of the Company's prior submission of an NDA for tenapanor for the treatment of IBS associated with constipation ("IBS-C"):

> Q – . . . . And so [ ] the NDA submission is completed [at] this point, right?
>
> * * *
>
> A – [Defendant Raab] Yes . . . And we've been guiding the traditional 10 plus 2 PDUFA. Now the fact that we have, the idea CNDA is actually 10 month PDUFA, neither first the full 12. ***So, as we communicate and have people understand the FDA has already seen the entire CMC*** [Chemistry, Manufacturing, and Controls] ***package, but for the dosage forms***, 10 20 and 30, ***they've seen majority [of] the clinical data and in fact cardiorenal consulted with GI*** [the gastrointestinal division] ***on the [renal] studies that were in that data package. So we're quite confident with what it is that we've submitted. The interactions [so] far with the agency have gone exceedingly well,*** will there be an inspection who knows with COVID, the confidence I have in the team and the confidence with the fact that

[20] *See* Transcript of Jefferies Virtual London Healthcare Conference at 3 (Nov. 17, 2020) (accessed via the Bloomberg Terminal).

> they've seen the majority of this helps a lot with the uncertainty we all feel until COVID has passed.[21]

[Emphasis added.]

70. The representation that meetings with the FDA were going "exceedingly well" was false and misleading. First, Raab did not believe that the meetings with the FDA had gone "exceedingly well" because he knew that in the pre-NDA meeting, the FDA had set an approval standard that Ardelyx could not meet and, therefore, that the NDA was at a high risk of rejection. Second, for the same reasons, Raab's statement lacked a reasonable basis and his failure to disclose these facts rendered his statement misleading. Third, these facts strongly cut against the factual representation made by Raab and his failure to disclose them rendered his misstatement misleading. The point of Raab's statement was that investors should have confidence in the likelihood of approval because the FDA looked favorably on the NDA. In fact, the exact opposite was true given the FDA's consistent guidance regarding what was required to obtain approval.

G. February 24, 2021 Investor Presentation

71. Defendant Raab gave a presentation to investors, on behalf of Ardelyx, in question-and-answer format at the 10th Annual SVB Leerink Global Healthcare Conference on February 24, 2021. Ardelyx published notice that the Company would be making that presentation – which it called a "fireside chat" – in a February 17, 2021 press release titled "Ardelyx to Present at the 10th Annual SVB Leerink Global Healthcare Conference."

72. During the presentation, Defendant Raab was asked about the status of Ardelyx's tenapanor NDA, in response to which he emphasized that certain divisions of the FDA "ha[d] seen a good portion of this package" when Ardelyx previously had submitted an NDA for tenapanor for the treatment of IBS-C. Defendant Raab espoused points substantially similar to those he made during the November 17, 2020 investor call in which he partook months before, purporting to

[21] *See* Transcript of Jefferies Virtual London Healthcare Conference at 4 (Nov. 17, 2020) (accessed via the Bloomberg Terminal). While the transcript indicates that Defendant Raab said "cardiorenal consulted with GI on the *green all* studies," an audio recording of the same presentation accessed from the Bloomberg Terminal confirms Defendant Raab said "cardiorenal consulted with GI on the *renal* studies."

leverage Ardelyx's prior successful tenapanor NDA for IBS-C as a favorable indicator of things to come:

> Q – Maybe this is a good time to ask you about how the FDA review is coming along and your confidence level in a timely approval, especially considering that at least in the last couple of months, some companies saw a delay due to COVID. Do you worry about that at all?
>
> A – Yes. I mean we always worry because you don't know until you know. And I think we've got confidence in this, though, because remember that this is – tenapanor has already been approved for another indication. So this NDA is what the FDA has already seen.
>
> And in fact, cardiorenal division consulted the GI [gastrointestinal] division for the approval of IBSRELA for IBS-C. Now IBSRELA is sitting on the shelf, but the benefit of that process we went through, both with the inspections that we went through as well as cardiorenal having seen a good portion of this package gives us confidence that the PDUFA date of April 29 is not something that's at massive risk.
>
> ***All the interactions that we've had thus far with the agency are standard ones that you have throughout the process of requests that they have for data or clarifications. But there's been nothing untoward and anything that causes us concern.***[22]

[Emphasis added.]

73. The representations that the FDA had said "nothing untoward" and had not said "anything that causes us concern" were false and misleading. First, Raab did not believe that the FDA had said "nothing untoward" and had not said "anything that causes us concern" because he knew that in the pre-NDA meeting, the FDA had set an approval standard that Ardelyx could not meet and, therefore, that the NDA was at a high risk of rejection. Second, Raab's statements lacked a reasonable basis and his failure to disclose these facts rendered his statements misleading. Third, these facts strongly cut against the factual representations made by Raab and his failure to disclose these facts rendered his misstatement misleading. The point of Raab's statement was that investors should have confidence in the likelihood of approval because the FDA had not said

[22] While the Thomson Reuters transcript available on BamSEC.com indicates that Defendant Raab said "unpoured," an audio recording of the same presentation accessed from the Bloomberg Terminal confirms Defendant Raab said "untoward."

anything raising the risk of rejection. In fact, the exact opposite was true given the FDA's consistent guidance regarding what was required to obtain approval.

H. March 8, 2021 Annual Report

74. On March 8, 2021, Ardelyx filed with the SEC on Form 10-K its fourth quarter and full year 2020 financial results ("FY20 10-K"), repeating substantially the same claims made in the Company's 2Q20 10-Q and 3Q20 10-Q, with respect to the tenapanor NDA and underlying Phase 3 Trials. In relevant part, the FY20 10-K stated:

> ***The NDA is supported by three successful Phase 3 trials*** involving over 1,000 patients that evaluated the use of tenapanor for the control of serum phosphorus in CKD patients on dialysis, with two trials evaluating tenapanor as monotherapy and one trial evaluating tenapanor as part of a dual mechanism approach with binders.
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> * * *
>
> In December 2019, ***we reported statistically significant topline efficacy results from our second monotherapy Phase 3 clinical trial***, the PHREEDOM trial, which evaluated tenapanor for the control of serum phosphorus in CKD patients on dialysis. The PHREEDOM trial followed ***a successful monotherapy Phase 3 clinical trial completed in 2017, the BLOCK trial, which achieved statistical significance for the primary endpoint***. The only adverse event reported in these Phase 3 trials in less than 5% of patients was diarrhea, with an incidence rate of 52% in the PHREEDOM trial and 39% in the BLOCK trial, with most incidences in each trial being mild to moderate in nature. PHREEDOM is a one-year study with a 26-week open-label treatment period and a 12-week double-blind, placebo-controlled randomized withdrawal period followed by a 14-week open-label safety extension period. An active safety control group, for safety analysis only, received sevelamer, open-label, for the entire 52-week study period. Patients completing the PHREEDOM trial from both the tenapanor arm and the sevelamer active safety control arm had the option to participate in NORMALIZE, an ongoing open-label 18-month extension study.
>
> * * *
>
> Tenapanor, if approved, would be the first therapy for phosphate management that blocks phosphorus absorption at the primary pathway of uptake. It is not a phosphate binder. Tenapanor is a novel, potent, small molecule, that ***has been shown in phase 3 studies to treat hyperphosphatemia as monotherapy and as a dual mechanism approach***.

[Emphasis added.]

75. The representation that the Company's Phase 3 studies were "successful" and that the Company's "phase 3 studies" had "shown" that tenapanor treated hyperphosphatemia as a monotherapy were false and misleading because Defendants were aware of undisclosed facts that seriously undermined the statement's accuracy and that rendered the statement as lacking a reasonable basis. A reasonable investor informed that Phase III trial results had "shown" something to be the case would expect that the speaker had a factual basis for its belief that such results were relevant or meaningful. Such an investor would expect that the speaker's proposed interpretation of trial results had not already been undermined by the agency tasked with evaluating the NDA. Here, Defendants knew but failed to disclose that the FDA had already indicated that tenapanor's efficacy data was insufficient to support approval. In the March 2020 pre-NDA meeting, the FDA told Ardelyx that its NDA would not be approved without evidence of a clinically meaningful treatment effect. The FDA had further discussed with Ardelyx the type of data that would suffice: (i) evidence of a treatment effect comparable to effects achieved by existing treatments, or (ii) data from clinical outcome trials. Defendants knew that they did not have either type of data. The efficacy data for tenapanor showed it to be one-third to one-half as effective as existing treatments and the Company had not done an outcome study. Thus, as discussed with the FDA in March 2020, Ardelyx faced a high chance of failure and delay.

76. The Annual Report also included several highly general, non-specific, statements about problems that the Company could hypothetically face in the future. The Company stated:

> The testing and approval processes require substantial time, effort and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all. ***Even if we believe a clinical trial has demonstrated safety and efficacy of one of our drug candidates for the proposed indication, the results may not be satisfactory to the FDA***. Nonclinical and clinical data may be interpreted by the FDA in different ways, which could delay, limit or prevent regulatory approval.

[Emphasis added.]

77. The foregoing statement was misleading because it spoke about the risk of FDA disagreement in a completely theoretical and general manner, referring to the risk of FDA disagreement arising with respect to any drug developed by the Company at any time. In so doing,

the representation misled investors into believing that there were no specific, material disagreements raised by the FDA at the time of the statement, which was incorrect. In fact, at the time, the FDA had set an approval standard for the tenapanor NDA that the Company could not satisfy with existing data and, in so doing, raised a serious risk that the tenapanor NDA would be rejected.

78. Similarly, the Annual Report misleadingly claimed that the "commercial success" of tenapanor depended on whether "tenapanor's safety and efficacy profile is satisfactory to the FDA and foreign regulatory authorities."

79. The foregoing statement was misleading because it spoke about the risk of a government somewhere in the world taking issue with tenapanor's efficacy profile in hypothetical and generic terms. In so doing, the representation misled investors into believing that there were no specific, material issues raised by the FDA with tenapanor's efficacy profile at the time of the statement, which was incorrect. In fact, at the time, the FDA had made clear that unless the Company submitted efficacy data showing that tenapanor was as effective as existing treatments or data from an outcome study, approval was highly unlikely. Further, Ardelyx's efficacy data showed that tenapanor was not as effective as existing treatments in that in reduced only one-third to one-half as much serum phosphorus as existing treatments, meaning that Ardelyx knew that there was a very high likelihood of rejection based on the stated comments of the FDA.

I. April 29, 2021 Press Release

80. On April 29, 2021 – the date the FDA initially set as the operative PDUFA date for the tenapanor NDA – Ardelyx issued a press release titled, "Ardelyx Announces Extension of the PDUFA Review Period for Tenapanor for the Control of Serum Phosphorus in Adult Patients with CKD on Dialysis," announcing that the FDA made a request for additional information "***to help the agency better understand the clinical data in light of tenapanor's novel mechanism of action as compared to approved therapies***." The Company reported that it "submitted the requested analyses" to the FDA in response to the request, which "constitute[d] a major amendment" to the

NDA that required extending the PDUFA date "by three months" to July 29, 2021. [Emphasis added.]

81. Quoting Defendant Raab, the press release stated,

> "While disappointed in the delay, we understand the impact that the COVID-19 pandemic has had on the operations of the agency," said Mike Raab, president and chief executive officer of Ardelyx. "We appreciate the constructive labeling discussions with the agency over the past month and ***believe that the additional analyses submitted in response to recent dialogue with the agency reinforce the extensive clinical evidence we generated on tenapanor***. We look forward to continuing to work closely and constructively with FDA during the remainder of the review process. We are confident in the comprehensive data set, are well prepared for the launch of tenapanor upon potential approval and are dedicated to bringing this important medicine to patients."
>
> The NDA for tenapanor for the control of serum phosphorus is supported by a comprehensive development program involving more than 1,000 patients, including ***three Phase 3 clinical trials, all of which met their primary and key secondary endpoints***.

[Emphasis added.]

82. Raab's representation that he believed that the "additional analyses submitted in response to recent dialogue with the agency reinforce the extensive clinical evidence we generated on tenapanor" is misleading because it creates a misimpression regarding the likelihood for approval. This representation lacked a reasonable basis and was severely undercut by the fact that the FDA had set an evidentiary standard that Ardelyx could not meet because the data from the Phase III trials showed that tenapanor only had a modest treatment effect, far less than what the FDA told Ardelyx it needed to be approved.

J. May 6, 2021 Press Release

83. As reported in the May 6, 2021 press release accompanying the Company's release of its First Quarter 2021 Financial Results, Defendant Raab offered an optimistic take on the FDA's request for clarifying information, stating in relevant part:

> "We continue to prepare for the potential approval and launch of tenapanor following the recent extension of our PDUFA date to July," said Mike Raab, president and chief executive officer of Ardelyx. "***We remain confident in the comprehensive data included in our New Drug Application*** and believe tenapanor represents an attractive alternative to currently available therapies to control serum phosphorus in CKD patients on dialysis. To that end, we are committed to working

> with the FDA through the completion of its review of our NDA and look forward to the possibility of making a significant impact in the lives of patients."

[Emphasis added.]

84. The representation that the Company "remain[ed] confident" in the "New Drug Application" was false and misleading. First, Raab was not "confident" in the NDA because he knew that in the pre-NDA meeting and other relevant communications, the FDA had set an approval standard that Ardelyx could not meet and, therefore, that the NDA was at a high risk of rejection. Second, Raab's statements lacked a reasonable basis and his failure to disclose these facts rendered his statements misleading. Third, these facts strongly cut against the factual representations made by Raab and his failure to disclose these facts rendered his misstatement misleading. The point of Raab's statement was that investors should have confidence in the likelihood of approval because, in Raab's view, the regulatory process had moved in a way that was indicative of approval. In fact, the exact opposite was true given the FDA's consistent guidance regarding what was required to gain approval.

IV. THE TRUTH EMERGES

85. Defendants' unduly rosy narrative came to a screeching halt after the markets closed on July 19, 2021. That day, Ardelyx announced the FDA sent the Company a letter six days earlier (on July 13, 2021), in which the FDA stated it had identified "deficiencies" with respect to "***the size of the treatment effect and its clinical relevance***" based on the clinical trial data Ardelyx provided in the tenapanor NDA. [Emphasis added.] Notably, this issue was the one raised by the FDA in the March 2020 pre-NDA meeting and that Defendants concealed with their blithe assurances that the FDA meetings were going exceedingly well.

86. The press release Ardelyx published on the topic stated, in relevant part:

> [T]oday [Ardelyx] announced that it received a letter from the U.S. Food and Drug Administration (the "FDA") on July 13, 2021, stating that, as part of its ongoing review of the company's New Drug Application ("NDA") for the control of serum phosphorus in adult patients with chronic kidney disease ("CKD") on dialysis, ***the FDA has identified deficiencies that preclude discussion of labeling and post-marketing requirements/commitments at this time***. The letter stated that the notification does not reflect a final decision on the information under review. The company immediately requested a meeting to discuss the deficiencies and was notified by the FDA today that the request for a meeting was denied.

> While the FDA has not provided specific details regarding the deficiencies, ***the FDA noted that a key issue is the size of the treatment effect and its clinical relevance***.
>
> "This is an extremely disheartening and disappointing communication from the FDA, particularly following the weeks of label discussions that occurred in early April, the fact that our NDA submission included three pivotal trials across 1,000 patients, all which met their primary and key secondary endpoints, as well as the additional data analyses we submitted in late April in response to the FDA's requests," said Mike Raab, president and chief executive officer of Ardelyx. "We plan to work with the FDA to learn more about the identified deficiencies and will seek to resolve them as quickly as possible."

[Emphasis added.]

87. These disclosures informed the market that, contrary to Defendants' claims, the Company's meetings with the FDA had not gone "exceedingly well" and that the NDA was not on a glide path to approval. On this news, the price of Ardelyx's shares plunged from their July 19, 2021 closing price of $7.70 per share, to a July 20, 2021 close of just $2.01 per share. This represents a one-day drop of nearly 74%, or hundreds of millions of dollars in lost market capitalization.

88. Then, on July 29, 2021 – the operative PDUFA date following the major amendment to the NDA Ardelyx reported on April 29, 2021 – the Company issued a press release announcing that it "***received a Complete Response Letter***" from the FDA in response to the tenapanor NDA. [Emphasis added.] A Complete Response Letter ("CRL") is a response to an NDA by which the FDA tells a drug sponsor its review of the NDA is complete and the agency is not approving the application. The relevant press release was titled "Ardelyx Receives Complete Response Letter from U.S. FDA for New Drug Application for Tenapanor for the Control of Serum Phosphorus in Adult Patients with CKD on Dialysis."

89. According to Ardelyx, in relevant part, the Complete Response Letter stated the FDA determined "***the magnitude of the treatment effect***" shown in the tenapanor NDA and underlying clinical trial data was "***small and of unclear clinical significance***":

> [T]oday [Ardelyx] announced that it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the company's New Drug Application (NDA) for tenapanor for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis.

> According to the CRL, while the FDA agrees that "the submitted data provide substantial evidence that tenapanor is effective in reducing serum phosphorus in CKD patients on dialysis," ***they characterize the magnitude of the treatment effect as*** "***small and of unclear clinical significance***." Additionally, the FDA noted that for the application to be approved, Ardelyx needs "to conduct an additional adequate and well-controlled trial ***demonstrating a clinically relevant treatment effect on serum phosphorus or an effect on the clinical outcome thought to be caused by hyperphosphatemia in CKD patients on dialysis***." There were no safety, clinical pharmacology/biopharmaceutics, CMC [chemistry, manufacturing, and controls] or non-clinical issues identified in the CRL.
>
> * * *
>
> "We are saddened by this communication from the FDA and what it means for the patients and the physicians who treat them," said Mike Raab, president and chief executive officer of Ardelyx. "We continue to believe tenapanor represents an important, first-in-class treatment option for patients with elevated phosphorus. We do not agree with the FDA's subjective assessment on ***the clinical relevance of the treatment effect of tenapanor in our studies which met all clinical endpoints agreed upon by the FDA***. In our view, the serum phosphorus lowering data generated with tenapanor in all of our clinical studies is meaningful and clinically significant. We will work with the agency to address the issues raised and, to the extent possible, find an expeditious path forward."

[Emphasis added.]

90. The CRL further stated that "there is no precedent for accepting treatment effects of the magnitude seen in this development program." A copy of the CRL letter is attached at pages 43–48 of Exhibit A.

91. Months later, during an investor presentation at the Jefferies London Healthcare Virtual Conference on November 18, 2021, Defendant Raab said the FDA's decision reflected the agency having "***moved . . . the goalposts*** on us [by] implying that they would expect an outcome type study":

> [A –] We clearly have a statistically significant impact on decreasing serum phosphorus whether it's a monotherapy or when you're adding it with binders, and you're having an impact. And physicians should be able to make those decisions based upon what the clinical data are that you have generated [from your] clinical studies. ***They have moved the [ ]goalposts on us, implying that they would expect an outcome type study*** which has never been required for phosphorus lowering drugs and that's a big part of our approach [is] to see – this is an acceptable endpoint. We hit the [endpoint] as we discussed and agreement [on the statistical] analysis plan. So we should address this in labeling and make sure that we have something that allows physicians to make a determination as to which patients are going to benefit from this.

[Emphasis added.]

92. Contrary to Defendant Raab's statements, however, Ardelyx had been told repeatedly by the FDA that approval of the tenapanor NDA was dependent on showing either (i) that tenapanor was at least as effective as existing treatments, meaning a reduction of serum phosphorus in the range of 1.5 to 2.2. mg/dL, or (ii) evidence from a clinical outcome trial showing that tenapanor improved recipients' health.

93. Following the issuance of the CRL, the Company undertook steps to appeal the denial of the tenapanor NDA through the FDA's formal dispute resolution procedures. First, the Company appealed to the Office of Cardiology, Hematology, Endocrinology and Nephrology, which the FDA denied. A copy of the denial letter, dated February 4, 2022, is attached at pages 49–59 of Exhibit A. Then the Company appealed to the Office of New Drugs, which convened an Advisory Committee meeting of the Cardiovascular and Renal Division ("Advisory Committee"). A copy of the relevant letter from the FDA, dated April 15, 2022, is attached at pages 60–71 of Exhibit A. The Advisory Committee is a panel of experts that makes non-binding recommendations to the FDA on questions that the FDA brings to it.

94. On November 16, 2022, the Advisory Committee decided, by a nine-to-four vote of its members, that the benefits of administering tenapanor to adult CKD patients on dialysis outweighed its risks for the control of serum phosphorus as a monotherapy. The Committee also decided, by a ten-to-two vote of its members (with one member abstaining), that the benefits of tenapanor outweighed its risks when administered in combination with phosphate binders. Neither of these votes resulted in approval of the previously rejected tenapanor NDA. Rather, they were non-binding advisory votes on the specific questions presented by the FDA.

95. The Committee members' "yes" votes on the risk-benefit profile of tenapanor as a monotherapy were far from the ringing endorsements of the drug that Defendants touted during the Class Period. For instance, Dr. Noel Bairey Merz explained that tenapanor was "probably better than nothing" for patients who "are otherwise . . . untreated" because they "are unable or

unwilling to take the standard of care."[23] Dr. Ed Kasper acknowledged that tenapanor was "not as effective as current therapy."[24] Dr. Javed Butler's vote was "a reluctant yes" because he believed "this still probably deserves a higher bar of efficacy."[25] Dr. Julia Lewis stated that "patients would always welcome another choice" in therapies.[26]

96. The Committee members' "no" votes on the risk-benefit profile of tenapanor as a monotherapy were consistent with the concerns the FDA expressed to the Company repeatedly during the drug's development and the first NDA process. Dr. O'Connor stated that "the degree of efficacy was modest," and cited the Company's use of "a surrogate endpoint that hasn't been validated thoroughly with clinical outcomes."[27] Dr. Ian de Boer "believe[d] there are insufficient clinical data to support the clinical benefits of this intervention."[28] Dr. Patrick Nachman cited "the small magnitude of the effect of tenapanor on serum phosphorus compared to placebo and apparent lesser magnitude of effect compared to currently proved agents," and also observed that "the patient populations" for whom the drug would work "seems to be quite small."[29]

97. Although the vote of the Advisory Committee was not binding on the Office of New Drugs in ruling on the Company's second-level appeal of the issuance of the CRL, the Office of New Drugs granted the appeal on December 29, 2022. The grant of that appeal did not amount to an approval of the tenapanor NDA. Rather, the FDA directed the Company that it must submit a new NDA for tenapanor to treat hyperphosphatemia in adult CKD patients on dialysis. On December 29, 2022, the Company announced it intended to do so in the first half of 2023.

98. In connection with the NDA resubmission, the Office of New Drugs also directed the FDA's Division of Cardiology and Nephrology to work with the Company to develop an

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[23] FDA Transcript at 287:3–12.

[24] *Id.* at 288:14.

[25] *Id.* at 289:22–290:6.

[26] *Id.* at 290:14–15.

[27] *Id.* at 287:17–19.

[28] *Id.* at 288:21–289:1.

[29] *Id.* at 291:18–292:4.

appropriate label for the drug to be considered in the resubmitted NDA. In a press release issued that day, the Company announced it "believe[d] that [such] a label could reflect an indication for patients ***whose hyperphosphatemia is insufficiently managed on binder therapy***." [Emphasis added.]

99. The Company announced the resubmission of its tenapanor NDA in a press release on April 18, 2023. The indication for which it sought approval with the resubmitted NDA was significantly narrower than the indication for which it sought approval in the first tenapanor NDA, however. Although the first tenapanor NDA sought approval for tenapanor "for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis," the second tenapanor NDA sought approval for tenapanor "for the control of serum phosphate in adult patients with chronic kidney disease on dialysis ***who have had an inadequate response or intolerance to a phosphate binder therapy***." [Emphasis added.] In other words, Ardelyx essentially accepted the FDA's position on efficacy by seeking a label that allows for the prescription of tenapanor only when a more effective existing treatment is not working or not tolerated.

100. The FDA accepted, or agreed to review, the resubmitted tenapanor NDA on May 17, 2023, and provided a six-month review timeline. The FDA approved the resubmitted NDA on October 17, 2023, a greater-than-two-years delay from the timeline Raab had told investors they should rely on.

101. The label that the FDA ultimately approved for tenapanor was limited to the narrower indication the resubmitted NDA sought approval of: "XPHOZAH [the trade name for tenapanor] is indicated to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis ***as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy***."[30]

102. The difference between the indication the Company initially sought approval for and the indication the FDA ultimately approved has commercial consequences. Simply put,

[30] U.S. Food & Drug Admin., FDA Label, XPHOZAH, https://nctr-crs.fda.gov/fdalabel/services/spl/set-ids/c57e279c-0f1b-4238-81b7-4e0dc0cc60c5/spl-doc?hl=tenapanor.

tenapanor as a therapy for any persons with hyperphosphatemia represented a market opportunity much larger than tenapanor as a therapy for persons who cannot tolerate or do not respond to phosphate binders.

V. ADDITIONAL SCIENTER ALLEGATIONS

103. Defendant Raab knew throughout the Class Period that the FDA had imposed a clinical relevance evidentiary standard on the tenapanor NDA that strongly imperiled the approval of the NDA. As CEO, Defendant Raab received the November 2017 Advice Letter from the FDA, which first raised the issue of Ardelyx needing to prove tenapanor's clinical relevance. He also received the 2018 Advice Letter from the FDA. Defendant Raab did not attend the March 2020 pre-NDA meeting where the FDA "clarified" that the NDA would not be approved unless (i) the clinical data showed that tenapanor's treatment effect was comparable with the 1.5 to 2.2 mg/dL effect achieved by existing treatments, or (ii) the Company came forward with data from an outcome trial. However, Defendant Raab was briefed on the substance of the FDA's message by the senior members of Ardelyx's management who did attend. Moreover, as evidenced by his Class Period statements characterizing the status of the FDA process and the views of the FDA, Defendant Raab closely tracked the feedback to the Company from the FDA. Defendant Raab was the architect of the Company's high-risk decision to ignore the comments of the FDA and attempt to achieve approval by reversing the Agency's consistent position on the data needed to show clinical relevance.

104. Defendant Raab benefited economically from investor perceptions that approval of the NDA was likely and had motive to fostering that perception notwithstanding the true facts to the contrary. As alleged above, approval of the NDA was highly material to the value of Ardelyx stock. In 2019, well before the submission of the NDA, the average price of Ardelyx stock was lower than during the Class Period and Raab sold only 29,698 shares of Ardelyx for proceeds of $58,969. At the end of 2019, a time when expectations of tenapanor's commercialization had begun to boost Ardelyx's stock price, Defendant Raab enacted a 10(b)5-1 plan. Pursuant to that plan, Raab sold 25,000 shares on February 5, 2020, at prices ranging from $7.19 to $7.45 a share

for proceeds of $182,928; 31,551 shares on March 2, 2020, at prices ranging from $7.00 to $7.065 a share for proceeds of $221,145; a total of 20,428 shares between April 15-17, 2020, at prices ranging from $7.00 to $7.045 a share for proceeds of $143,325; a total of 20,427 shares between May 4-5, 2020, at prices ranging from $7.00 to $7.04 per share for proceeds of $143,222; 23,128 shares on June 1, 2020, at prices ranging from $7.17 to $7.50 per share for proceeds of $169,635; and 23,128 shares on July 2, 2020, at prices ranging from $7.00 to 7.065 per share for proceeds of $162,130. Defendant Raab continued thereafter to sell shares pursuant to open market sales. Defendant Raab sold 106,337 shares on September 15, 2020, at prices ranging from $5.30 to $5.78 per share for proceeds of $596,285; 2,534 shares on February 22, 2021, at $6.88 a share for proceeds of $17,440; and 2,534 shares on May 20, 2021, at $7.09 for proceeds of $17,960.

105. While Defendant Raab has continued to sell stock since the rejection of Ardelyx's NDA, he has received far less in proceeds because the stock price of Ardelyx was much lower. Defendant Raab also sold less stock overall. Between January 1, 2020 and July 2021, Defendant Raab sold 255,067 shares for proceeds of $1,654,070. In the nineteen months from August 2021 through March 2023, Defendant Raab sold 146,971 shares for proceeds of $140,209. Between March 2023 and the present, Defendant Raab sold 58,579 shares for proceeds of $343,172. A copy of Defendant Raab's sales between January 1, 2019, and the present is attached hereto as Exhibit C.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

106. Plaintiff repeats and realleges each and every allegation contained in paragraphs 1 through 105 above as if fully set forth herein.

107. Plaintiff brings this action as a class action, pursuant to Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure, on behalf of a class consisting of all those who purchased, or otherwise acquired Ardelyx's common stock, during the Class Period, and were damaged upon the revelation of the alleged corrective disclosure (the "Class").

108. Excluded from the Class are: (i) Defendants; (ii) present or former executive officers of Ardelyx, members of the Company's Board of Directors, and members of their

immediate families (as defined in 17 C.F.R. §229.404, Instructions (1)(a)(iii) and (1)(b)(ii)); (iii) any of the foregoing persons' legal representatives, heirs, successors, or assigns; and (iv) any entities in which Defendants have or had a controlling interest, or any affiliate of Ardelyx.

109. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, the Company's common stock was actively traded on the NASDAQ, a national securities exchange in the United States. While the exact number of Class members is unknown to Plaintiff at this time, and can only be ascertained through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the Class. Millions of Ardelyx shares were publicly traded during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by Ardelyx or its transfer agent and may be notified of the pendency of this action by mail, using a form of notice similar to that customarily used in securities class actions.

110. Plaintiff's claims are typical of the claims of Class members because all members of the Class are similarly affected by Defendants' wrongful conduct in violation of the federal securities laws as alleged herein.

111. Plaintiff will fairly and adequately protect the interests of Class members and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

112. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the members of the Class are:

(a) whether Defendants violated the Exchange Act as alleged herein;

(b) whether Defendants' statements to the investing public during the Class Period omitted and/or misrepresented material facts about the Company;

(c) whether Defendants' statements to the investing public during the Class Period omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) whether Defendants Raab and Rosenbaum caused Ardelyx to issue false and misleading statements during the Class Period;

(e) whether Defendants acted knowingly or recklessly in issuing false and misleading statements;

(f) whether the price of Ardelyx's common stock was artificially inflated; and

(g) whether the members of the Class have sustained damages, and, if so, what is the proper measure of damages.

113. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable.

114. Further, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for Class members to individually redress the wrongs done to them. There will be no difficulty in the management of this Action as a class action.

PRESUMPTION OF RELIANCE

115. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) the omissions and misrepresentations were material;

(c) Ardelyx's common stock is traded in an efficient market;

(d) the Company's securities were liquid and traded with moderate to heavy volume during the Class Period;

(e) the Company's securities were traded on the NASDAQ in the United States;

(f) the Company was covered by securities analysts;

(g) the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

(h) Plaintiff and members of the Class purchased, acquired, and/or sold Ardelyx's common stock between the time the Defendants failed to disclose, or misrepresented material facts, and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

116. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

117. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

CLAIMS FOR RELIEF

COUNT I

Violations of §10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder (Against All Defendants)

118. Plaintiff repeats and realleges each and every allegation contained in paragraphs 1 through 117 above, as if fully set forth herein.

119. This Count is asserted on behalf of all members of the Class against Ardelyx and the Individual Defendants for violations of §10(b) of the Exchange Act (15 U.S.C. §78(b)) and Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5).

120. During the Class Period, Defendants engaged in a plan, scheme, conspiracy, and course of conduct pursuant to which they knowingly or recklessly engaged in acts, transactions, practices, and courses of business that operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes, and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Ardelyx's

common stock; and (iii) cause Plaintiff and other members of the Class to purchase, or otherwise acquire, Ardelyx's common stock at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, Defendants took the actions set forth herein.

121. Pursuant to the above plan, scheme, conspiracy, and course of conduct, Defendants participated directly or indirectly in the preparation and/or issuance of the annual reports, SEC filings, press releases, and other statements and documents, as described above, including statements made to securities analysts and the media, that were designed to influence the market for Ardelyx's common stock. Such reports, filings, releases, and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Ardelyx's business and operations.

122. By virtue of their positions at Ardelyx, the Individual Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein, and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, the Individual Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Individual Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew, or recklessly disregarded, that material facts were being misrepresented or omitted, as described above.

123. Further information showing that Defendants acted knowingly, or with reckless disregard for the truth, is peculiarly within Defendants' knowledge and control. As senior managers and/or directors of Ardelyx, the Individual Defendants had knowledge of the details of Ardelyx's internal affairs.

124. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, Defendants Raab and Rosenbaum were able to, and did, directly or indirectly, control the content of the statements of Ardelyx. As officers and/or directors of a publicly held company, Defendants Raab and

Rosenbaum had a duty to disseminate timely, accurate, truthful, and complete information with respect to Ardelyx's businesses, operations, future financial condition, and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases, and public statements, the market price of Ardelyx's common stock was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Ardelyx's business and financial condition, which were concealed by Defendants, Plaintiff and other members of the Class purchased, or otherwise acquired Ardelyx's common stock, at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities, and/or statements disseminated by Defendants, and were damaged thereby.

125. During the Class Period, Ardelyx's common stock was traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which Defendants made, issued, or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired Ardelyx's common stock at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased, or otherwise acquired, said common stock, or would not have purchased or otherwise acquired shares at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Ardelyx's common stock was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Ardelyx's common stock declined sharply upon public disclosure of the facts alleged herein, to the injury of Plaintiff and Class members.

126. By reason of the conduct alleged herein, Defendants have knowingly or recklessly, directly or indirectly, violated §10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

127. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their respective purchases, acquisitions, and sales of the Company's securities during the Class Period, upon the disclosure

that the Company had been disseminating misrepresented financial statements to the investing public.

128. This action was filed within two years of discovery of the fraud and within five years of Plaintiff's purchase of securities giving rise to the cause of action.

COUNT II

Violations of §20(a) of the Exchange Act
(Against the Individual Defendants)

129. Plaintiff repeats and realleges each and every allegation contained in paragraphs 1 through 128 above, as if fully set forth herein.

130. During the Class Period, the Individual Defendants participated in the operation and management of Ardelyx and conducted and participated, directly and indirectly, in the conduct of Ardelyx's business affairs. Because of his senior positions as the Company's CEO and President, Defendant Raab knew of the materially false and misleading information alleged herein. Similarly, because of his senior position as the Company, Defendant Rosenbaum knew of the materially false and misleading information alleged herein.

131. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information, with respect to Ardelyx's business practices, and promptly correct any public statements issued by Ardelyx that had become materially false or misleading.

132. Because of their positions of control and authority as senior directors, and/or officers, and/or executive team members of the Company, the Individual Defendants were able to, and did, control the contents of the various reports, press releases, and public filings that Ardelyx disseminated in the marketplace during the Class Period concerning the Company's business, operations, and the tenapanor NDA. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Ardelyx to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were each a "controlling person" of Ardelyx within the meaning of §20(a) of the Exchange Act. In this capacity, the Individual Defendants

participated in the unlawful conduct alleged herein, that artificially inflated the market price of Ardelyx's common stock.

133. The Individual Defendants, therefore, each acted as a controlling person of Ardelyx. By reason of their senior management positions and/or being a director of Ardelyx, the Individual Defendants had the power to direct the actions of, and exercised the same, to cause Ardelyx to engage in the unlawful acts and conduct complained of herein. The Individual Defendants exercised control over the general operations of Ardelyx, and possessed the power to control the specific activities that comprise the primary violations, about which Plaintiff and the other members of the Class complain.

134. As set forth above, Ardelyx and the Individual Defendants each violated §10(b) and Rule 10b-5 promulgated thereunder by their acts and omissions, as alleged in this complaint.

135. By reason of the above conduct and by virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to §20(a) of the Exchange Act. As a direct and proximate result of the Individual Defendants' wrongful conduct, Plaintiff and the other members of the Class have suffered damages in connection with their purchases of the Company's securities.

136. This action is filed within two years of discovery of the fraud and within five years of Plaintiff's purchase of securities giving rise to the cause of action.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

A. Determining that the instant action may be maintained as a class action under Fed. R. Civ. P. 23, and certifying Plaintiff as the Class Representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class pre- and post-judgment interest, as well as their reasonable attorneys' fees, expert fees, and other costs; and

D. Awarding Plaintiff and the other Class members such other relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Pursuant to Fed. R. Civ. P. 38(b), Plaintiff hereby demands a trial by jury on all issues so triable.

DATED: April 19, 2024

SCOTT+SCOTT
ATTORNEYS AT LAW LLP

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Counsel for Lead Plaintiff
Jatin Malhotra and the Proposed Class

CERTIFICATE OF SERVICE

I hereby certify that on April 19, 2024, I caused the foregoing document to be filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the email addresses denoted on the Electronic Mail Notice List.

Executed on April 19, 2024, at New York, New York.

/s/ Thomas L. Laughlin, IV
Thomas L. Laughlin, IV